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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS NORTH AMERICA, INC., TAKEDA PHARMACEUTICALS LLC, TAKEDA PHARMACEUTICALS AMERICA, INC., and ETHYPHARM, S.A., Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC. and CADILA HEALTHCARE LIMITED, Defendants.	:	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL RULE 11.2**

Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals North America, Inc., Takeda Pharmaceuticals LLC, and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda") and Ethypharm, S.A. ("Ethypharm") (Takeda and Ethypharm together, "Plaintiffs"), as and for their Complaint against defendants Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Limited (together, "Defendants"), allege as follows:

THE PARTIES

1. Plaintiff Takeda Pharmaceutical Company Limited ("Takeda Japan") is a Japanese corporation, having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka, Japan. As part of its business, Takeda Japan is involved in the research, development, and marketing of pharmaceutical products.

2. Plaintiff Takeda Pharmaceuticals North America, Inc. ("TPNA") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, TPNA is involved in the research, development, and marketing of pharmaceutical products. TPNA has the exclusive right to import lansoprazole orally-disintegrating tablets and to sell them to Takeda Pharmaceuticals LLC.

3. Plaintiff Takeda Pharmaceuticals LLC ("Takeda LLC") is a Delaware limited liability company, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, Takeda LLC is involved in the purchase and sale of pharmaceutical products. Takeda LLC is the exclusive licensee of U.S. Patent No. 6,328,994 ("the '994 Patent") and U.S. Patent No. 7,431,942 ("the '942 Patent"), and is the exclusive sublicensee in the field of use for lansoprazole of U.S. Patent No. 5,464,632 ("the '632 Patent").

4. Plaintiff Takeda Pharmaceuticals America, Inc. ("Takeda America") is a Delaware corporation, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015. As part of its business, Takeda America is involved in the purchase, sale and marketing of pharmaceutical products. Takeda America has the exclusive right to sell lansoprazole orally-disintegrating tablets to the public under the patents.

5. Plaintiff Ethypharm, S.A. ("Ethypharm") is a French corporation, having a principal place of business at 21 rue Saint Matthieu 78550, Houdan, France. As part of its business, Ethypharm is involved in the research, development, manufacturing, and licensing of pharmaceutical products. Ethypharm appears as a plaintiff in this action solely by virtue of being the record owner of the '632 Patent. Ethypharm seeks relief in this action solely with respect to the '632 Patent.

6. On information and belief, defendant Zydus Pharmaceuticals (USA) Inc.("Zydus") is a New Jersey corporation, having a principal place of business located at 210 Carnegie Center, Suite 103, Princeton, NJ 08540 and is engaged in the manufacture and sale of pharmaceutical products.

7. On information and belief, defendant Cadila Healthcare Limited ("Cadila") is an Indian corporation, having a principal place of business located at Zydus Tower, Satellite Cross Roads, Ahmedabad – 380015 Gujarat, India. On information and belief, Cadila manufactures bulk pharmaceutical products.

8. On information and belief, Zydus is a wholly owned subsidiary of Cadila.

9. On information and belief, Zydus is controlled and/or dominated by Cadila.

10. On information and belief, Cadila conducts its North American operations, at least in part, through Zydus.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. Zydus is subject to personal jurisdiction in this District by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial and continuing contacts with the State.

13. On information and belief, Cadila regularly transacts business within this District, including but not limited to directing the operations and management of Zydus, as well as shipping pharmaceuticals to Zydus from locations outside the United States for distribution by Zydus within the United States generally, and within this District specifically.

14. On information and belief, Zydus acts as an agent of Cadila with respect to the acts complained of herein.

15. On information and belief, the acts of Zydus complained of herein were done at the direction of, with the authorization of, with the cooperation, participation, and assistance of, and/or, in part, for the benefit of Cadila.

16. On information and belief, Cadila directed Zydus to perform the acts complained of herein to, in whole or in part, shield itself from liability for patent infringement based upon those acts.

17. Zydus's acts and contacts with this District, as an agent of Cadila, are attributable to Cadila for jurisdictional purposes.

18. Cadila is subject to the personal jurisdiction in this District by virtue of, *inter alia,* its incorporation of Zydus in New Jersey, its conduct of business in this District, its purposeful availment of the rights and benefits of New Jersey law, and its substantial and continuing contacts with the State.

19. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b), (c) and (d), and 1400(b).

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

20. On December 11, 2001, the PTO issued the '994 Patent, entitled "Orally Disintegrating Tablets," to Takeda Chemical Industries, Ltd. (now Takeda Pharmaceutical Company Ltd.), the assignee of the named inventors Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata. Plaintiff Takeda Japan is the record owner of the '994 Patent, and Plaintiff Takeda LLC is the exclusive licensee. A copy of the '994 Patent is attached hereto as Exhibit A.

21. On October 7, 2008, the PTO issued the '942 Patent, entitled "Orally Disintegrable Tablets," to Takeda Pharmaceutical Company Limited, the assignee of the named inventors Toshihiro Shimizu, Shuji Morimoto, and Tetsuro Tabata. Plaintiff Takeda Japan is the record owner of the '994 Patent, and Plaintiff Takeda LLC is the exclusive licensee. A copy of the '942 Patent is attached hereto as Exhibit B.

22. On November 7, 1995, the PTO issued the '632 Patent, entitled "Rapidly Disintegratable Multiparticular Tablet," to Laboratoires Prographarm, the assignee of the named inventors Gerard Cousin, Etienne Bruna, and Edouard Gendrot. Laboratoires Prographarm

granted Plaintiff Takeda Japan an exclusive license to the '632 Patent for lansoprazole with the right to sublicense. Plaintiff Ethypharm subsequently acquired Laboratoires Prographarm and is the record owner of the '632 Patent. Plaintiff Takeda Japan granted Plaintiff Takeda LLC an exclusive sublicensee to the '632 Patent for lansoprazole. On February 20, 2001, the PTO issued a Reexamination Certificate for the '632 Patent. A copy of the '632 Patent and its Reexamination Certificate is attached hereto as Exhibit C.

23. On August 30, 2002, the United States Food and Drug Administration ("FDA") approved New Drug Application ("NDA") No. 21-428 for lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg. Plaintiff TPNA is the holder of NDA No. 21-428 for lansoprazole delayed release orally disintegrating tablets, which Plaintiff Takeda America sells under the name Prevacid® SoluTab™.

24. The '994, '942, and '632 Patents (collectively, "the patents-in-suit") are listed in a FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (known as the "Orange Book") for Prevacid® SoluTab™, delayed release orally disintegrating lansoprazole tablets, 15 and 30 mg.

25. On information and belief, through the coordinated efforts of its staff worldwide, including in India and the United States, Cadila seeks to constantly expand the range of generic products it sells.

26. On information and belief, Zydus and Cadila collaborate in the manufacture, marketing and sale of many pharmaceutical products (including generic drug products manufactured and sold pursuant to an approved abbreviated new drug application) within the United States generally and the State of New Jersey specifically.

27. On information and belief, Cadila actively reviews pharmaceutical patents and seeks opportunities to challenge those patents.

28. On information and belief, Cadila reviewed the patents-in-suit and certain commercial and economic information relating to Prevacid® SoluTab™, including estimates of the revenues generated by the sale of Prevacid® SoluTab™, and decided to file an Abbreviated New Drug Application ("ANDA"), seeking approval to market lansoprazole delayed release orally disintegrating tablets.

29. On information and belief, Zydus and Cadila collaborated in the research, development, preparation and filing of ANDA No. 200-816 for lansoprazole delayed release orally disintegrating tablets.

30. On information and belief, Zydus submitted to FDA ANDA No. 200-816 seeking approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets, 15 and 30 mg, prior to the expiration of the patents-in-suit.

31. Plaintiffs have received a letter dated February 19, 2010 from Zydus notifying them that Zydus's ANDA No. 200-816 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Zydus's opinion, the patents-in-suit are invalid and/or will not be infringed by the commercial manufacture, use or sale of the lansoprazole delayed release orally disintegrating tablet products described in ANDA No. 200-816.

32. On information and belief, Cadila made the ultimate decision to file ANDA No. 200-816 with the FDA, and encouraged and directed Zydus to file ANDA No. 200-816 with a Paragraph IV certification, and Zydus did so at Cadila's direction.

33. On information and belief, Cadila was necessarily aware of the patents-in-suit when it directed Zydus to file ANDA No. 200-816 with a Paragraph IV certification.

34. Plaintiffs commenced this action within 45 days of the date they received Zydus's notice of ANDA No. 200-816 containing the Paragraph IV certification.

35. On information and belief, Zydus and Cadila continue to collaborate in seeking approval of ANDA No. 200-816 from the FDA and intend to collaborate in the commercial manufacture, marketing, and sale of lansoprazole delayed release orally disintegrating tablets (including commercial marketing and sale of such products in the State of New Jersey) in the event that FDA approves ANDA No. 200-816.

FIRST CLAIM FOR RELIEF
(Direct Infringement of the '994 Patent by Zydus and Cadila)

36. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 35 hereof, as if fully set forth herein.

37. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '994 Patent.

38. By filing ANDA No. 200-816 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets products described therein, prior to the expiration of the '994 Patent, Defendants have infringed the '994 Patent under 35 U.S.C. § 271(e)(2).

39. Defendants were aware of the existence of the '994 Patent prior to filing ANDA No. 200-816 but took such action knowing that it would constitute infringement of the '994 Patent.

40. On information and belief, Defendants acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '994 Patent.

41. Defendants' conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

42. Takeda will be irreparably harmed if Defendants are not enjoined from infringing the '994 Patent.

SECOND CLAIM FOR RELIEF
(Inducement of Infringement of the '994 Patent by Cadila)

43. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 42 hereof, as if fully set forth herein.

44. Through the conduct alleged above, Cadila has knowingly and actively induced Zydus to infringe, and continue to infringe, one or more claims of the '994 Patent.

45. By reason of Cadila's inducement of Zydus's direct infringement of the '994 Patent, Cadila has caused and continues to cause irreparable harm to Takeda.

46. On information and belief, Cadila's inducement of Zydus's direct infringement of the '994 Patent will continue unless enjoined by this Court.

47. Takeda has no adequate remedy at law for Cadila's inducement of Zydus's direct infringement of the '994 Patent.

48. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Takeda's reasonable attorney fees reasonable attorney fees.

THIRD CLAIM FOR RELIEF
(Direct Infringement of the '942 Patent by Zydus and Cadila)

49. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 48 hereof, as if fully set forth herein.

50. Through the conduct alleged above, Defendants have directly infringed, and continue to directly infringe, one or more claims of the '942 Patent.

51. By filing ANDA No. 200-816 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets described therein, prior to the expiration of the '942 Patent, Defendants have infringed the '942 Patent under 35 U.S.C. § 271(e)(2).

52. Defendants were aware of the existence of the '942 Patent prior to filing ANDA No. 200-816 but took such action knowing that it would constitute an infringement of the '942 Patent.

53. On information and belief, Defendants acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '942 Patent.

54. Defendants' conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

55. Takeda will be irreparably harmed if Defendants are not enjoined from infringing the '942 Patent.

FOURTH CLAIM FOR RELIEF
(Inducement of Infringement of the '942 Patent by Cadila)

56. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 55 hereof, as if fully set forth herein.

57. Through the conduct alleged above, Cadila has knowingly and actively induced Zydus to infringe, and continue to infringe, one or more claims of the '942 Patent.

58. By reason of Cadila's inducement of Zydus's direct infringement of the '942 Patent, Cadila has caused and continues to cause irreparable harm to Takeda.

59. On information and belief, Cadila's inducement of Zydus's direct infringement of the '942 Patent will continue unless enjoined by this Court.

60. Takeda has no adequate remedy at law for Cadila's inducement of Zydus's direct infringement of the '942 Patent.

61. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Takeda's reasonable attorney fees.

FIFTH CLAIM FOR RELIEF
(Direct Infringement of the '632 Patent by Zydus and Cadila)

62. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 61 hereof, as if fully set forth herein.

63. Through the conduct alleged above, Defendants have directly infringed, and continues to directly infringe, one or more claims of the '632 Patent.

64. By filing ANDA No. 200-816 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use and sale of lansoprazole delayed release orally disintegrating tablets described therein, prior to the expiration of the '632 Patent, Defendants have infringed the '632 Patent under 35 U.S.C. § 271(e)(2).

65. Defendants were aware of the existence of the '632 Patent prior to filing ANDA No. 200-816 but took such action knowing that it would constitute an infringement of the '632 Patent.

66. On information and belief, Defendants acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '632 Patent.

67. Defendants' conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

68. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '632 Patent.

SIXTH CLAIM FOR RELIEF
(Inducement of Infringement of the '632 Patent by Cadila)

69. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 68 hereof, as if fully set forth herein.

70. Through the conduct alleged above, Cadila has knowingly and actively induced Zydus to infringe, and continue to infringe, one or more claims of the '632 Patent.

71. By reason of Cadila's inducement of Zydus's direct infringement of the '632 Patent, Cadila has caused and continues to cause irreparable harm to Plaintiffs.

72. On information and belief, Cadila's inducement of Zydus's direct infringement of the '632 Patent will continue unless enjoined by this Court.

73. Plaintiffs have no adequate remedy at law for Cadila's inducement of Zydus's direct infringement of the '632 Patent.

74. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

WHEREFORE, Plaintiffs respectfully request the following relief:

A. An order adjudging and decreeing that Zydus and Cadila have infringed the patents-in-suit;

B. An order adjudging and decreeing that Cadila has induced infringement of the patents-in-suit;

C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 200-816 be no earlier than the expiration date of the last of the patents-in-suit, including any extensions;

D. A preliminary and permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Zydus and Cadila, their officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the lansoprazole products described in ANDA No. 200-816 or any other ANDA not colorably different from ANDA No. 200-816 until the expiration date of the last of the patents-in-suit, including any extensions;

E. A declaration that this case is exceptional and an award of attorneys' fees under 35 U.S.C. § 285 and costs and expenses in this action; and

F. Such other and further relief as the Court may deem just and proper.

Respectfully submitted,

Dated: April 5, 2010

By: *s/William J. Heller*

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CERTIFICATION PURSUANT TO LOCAL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the above-captioned action is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Respectfully submitted,

Dated: April 5, 2010

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